K123633

510(k) Summary
Tissue Regeneration Systems, Inc
TRS Cranial Bone Void Filler
Traditional 510(k)

1.0 Manufacturer Name

Tissue Regeneration Systems, Inc.
5400 Carillon Point
Kirkland, Washington 98033

AUG 16 2013

2.0 Official Contact

Jim Fitzsimmons
Chief Executive Officer

Phone: 425-576-4032
Fax: 425-576-4040
E-mail: Jim@tissuesys.com

Alternate Contact

John Garinger
Director, Regulatory Affairs and Quality Assurance
Phone: 206-730-2815
Fax: 425-576-4040
E-mail: John@tissuesys.com

3.0 Date Prepared: November 16, 2012

4.0 Device Name and Classification

Proprietary Name:	**TRS PCL Cranial Bone Void Filler**
Common/Usual Name:	Bone void filler
Classification Name:	Burr Hole Cover
Regulation Number:	§882.5250
Device Class:	Class II
Classification Name:	GXR
Classification Panel:	Neurology

5.0 Indications for Use

TRS Cranial Bone Void Filler is intended for use in the repair of 13mm neurosurgical cranial burr holes. It should be gently packed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure.

6.0 Device Description

TRS Cranial Bone Void Filler (TRS C-BVF) is a synthetic, porous, osteoconductive, bone void filler made from PCL polycaprolactone $(C_6H_{10}O_2)X$ which will degrade and resorb fully in vivo by hydrolysis and is subsequently metabolized by the body, and hydroxylapatite $(Ca_{10}(PO_4)_6.(OH)_2)$ with a calcium phosphate bone mineral coating (Hydroxylapatite and Octacalcium phosphate). TRS BVF has an interconnected porous structure that acts as an osteoconductive matrix for the ingrowth of bone.

TRS C-BVF is available in single size, which is a 13mm diameter x 5mm "plug" with a 20mm diameter x .90mm thick flange.

TRS C-BVF is manufactured using a laser sintering process and is then coated with the calcium phosphate bone mineral coating. The product is shipped to a contract manufacturer who packages, labels and sterilizes the C-BVF devices. They are then returned to TRS and inventoried as Finished Goods.

7.0 Predicate Devices

Osteopore PCL Scaffold Bone Void Filler (BVF), (K051093, product code GXP cleared on March 17, 2006) Note: *This device would be cleared under product code GXR if it were reviewed using today's more product specific product codes.*

Synthes chronOS Composite resorbable bone void filler (K071046, product code MQV, cleared on October 23, 2007).

Synthes chronOS, porous, osteoconductive, resorbable bone void filler (K041350, product code GXP, cleared on July 8, 2004).

Synthes Rapid Resorbable Cranial Clamp burr hole cover (K041611, product code GXR, cleared on September 8, 2004.

8.0 Comparison to Marketed Devices

Tissue Regeneration Systems, Inc. purports the information contained in this 510(k) Submission demonstrates that the TRS Cranial Bone Void Filler is substantially equivalent to Osteopore PCL Scaffold Bone Void Filler cleared under K051093, Synthes chronOS Composite cleared under K071046, Synthes chronOS, cleared under K041350 and Synthes Rapid Resorbable Cranial Clamp cleared under K041611.

Table 6-1 Predicate Device Regulatory Comparison

Information	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Manufacturer	Tissue Regeneration Systems, Inc.	Synthes	Synthes	Osteopore	Synthes
Trade Name	TRS C-BVF	Synthes chronOS Composite	Synthes chronOS	Osteopore PCL Scaffold Bone Void Filler	CranioClamp - Bioabsorbable Cranial Bone Flap Fixation System
510(k) #	To Be Determined	K071046	K041350	K051093	K071138
Product Code	GXR	MQV	GXP	GXP	GXR
Regulation Number	882.55250	888.3045	882.5300	882.5300	882.5250
Classification Name	Burr Hole Cover	Resorbable Calcium Salt Bone Void Filler	Methylmethacrylate for Cranioplasty	Methylmethacrylate for Cranioplasty	Burr Hole Cover
Device Class	Class II	Class II	Class II	Class II	Class II
Classification Panel	Neurology	Orthopedic and Rehabilitation Devices	Neurology	Neurology	Neurology

Table 6-2: Device Characteristic Comparison

Characteristic	TRS C-BVF (subject device)	Synthes chronOS Ccomposite (predicate/reference)	Synthes chronOS (predicate device)	Osteopore PCL Scaffold (predicate device)	Synthes CranioClamp - Bioabsorbable Cranial Bone Flap Fixation System (predicate device)	Similar	Different
Materials	PCL (poly-ε-caprolactone), Hydroylapatite, Octacalcium Phosphate	PCL (polylactide-co-ε-caprolactone) matrix with imbedded β-Tricalcuim Phosphate granules.	β-Tricalcuim Phosphate granules.	PCL (poly-ε-caprolactone)	85:15 Poly (L-lactide-co-glycolide)	X	
	Bone contacting surface: Hydroxyapatite and Calcium Phosphate	Bone contacting surface: Calcium Phosphate	Bone contacting surface: Calcium Phosphate	Bone contacting surface: PCL (poly-ε-caprolactone)	Bone contacting surface:85:15 Poly (L-lactide-co-glycolide)	X	
	PCL Matrix	PCL Matrix	No PCL	PCL Matrix	No PCL	X	
	Ceramic Particles	Ceramic Particles	Ceramic Particles	No Ceramic Particles	No Ceramic Particles	X	
	Not intended to be trimmed	Can be trimmed with a scalpel or molded	Can be trimmed with a scalpel or molded	Can be trimmed with a scalpel	Not intended to be trimmed	X	
	Resorbable materials	Resorbable materials	Resorbable materials	Resorbable materials	Resorbable materials	X	
Biocompatible	Meets ISO 10993	Meets ISO 10993	Meets ISO 10993	Meets ISO 10993	Meets ISO 10993	X	
Design	Interconnected macroporous structure	Interconnected macroporous structure	Interconnected macroporous structure	Interconnected macroporous structure	Smooth surface	X	
	PCL Matrix	PCL Matrix	No PCL	PCL Matrix	No PCL	X	
	Ceramic Particles	Ceramic Particles	Ceramic Particles	No Ceramic Particles	No Ceramic Particles	X	
	Not intended to be trimmed	Can be trimmed with a scalpel or molded	Can be trimmed with a scalpel or molded	Can be trimmed with a scalpel	Not intended to be trimmed	X	
	Cylindrical plug with flange	Various forms/sizes	Various forms/sizes	Various forms/sizes	18 mm diameter disc	X	

Characteristic	TRS CBVF (subject device)	Synthes chronOS Composite (predicate/reference)	chronOS (predicate device)	Osteopore PCL Scaffold (predicate device)	CranioClamp - Bioabsorbable Cranial Bone Flap Fixation System	Similar	Different
Intended Use	Is intended to be gently packed or placed into bony voids or gaps of the skeletal system.	Is intended to be gently packed or placed into site.	Is intended to be gently packed or placed into site.	Is intended to be gently packed or placed into bony voids or gaps of the skeletal system.	Is intended for covering burr holes and for fixation of cranial bone flaps, in pediatric and adult patients.	X	
Indications for Use	Is indicated for use in the repair of neurosurgical cranial burr holes.	Is indicated for bony voids or gaps that are not intrinsic to the stability of the bony structure. Synthes chronOS Composite is indicated for use in the treatment of bony defects created surgically or through traumatic injury.	is intended for the repair or filling of craniofacial defects and craniotomy cuts with a surface area no larger than 25 cm^2. It is also indicated for the restoration or augmentation of bony contours of the craniofacial skeleton; including the fronto-orbital, malar and mental areas.	Is indicated for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects. It is also for use in the augmentation or restoration of bony contour in the craniofacial skeleton.	Is intended for covering burr holes and for fixation of cranial bone flaps, in pediatric and adult patients.	X	
Function	Fill bony voids or gaps of the skeletal system until the device is replaced by bone during the healing process.	Fill bony voids or gaps of the skeletal system until the device is replaced by bone during the healing process.	Fill bony voids or gaps of the skeletal system until the device is replaced by bone during the healing process.	Fill bony voids or gaps of the skeletal system until the device is replaced by bone during the healing process.	Covering burr holes and for fixation of cranial bone flaps	X	
Sterilization	Sterile Ethylene Oxide	Sterile Irradiation	Sterile Irradiation	Sterile Irradiation	Sterile	X	

Comparison to Marketed Devices continued: The subject device and the predicate devices have the same intended use, are of similar design, perform the same function and are composed of similar resorbable materials. The subject and predicate devices are osteoconductive and both provide an interconnected, porous scaffold and an environment for new bone ingrowth. Both devices are available in similar forms and are provided sterile. Both the subject and predicate devices are shown to be biocompatible, perform similarly in *in-vitro* and animal testing and are composed of component materials with a history of use in implantable medical devices.

9.0 Performance Testing

TRS Cranial Bone Void Filler has undergone a comprehensive battery of non-clinical testing, including chemical, physical, animal and biocompatibility. Testing has provided reasonable assurance of safety and effectiveness for its intended use and supports a determination of substantial equivalence.

9.1 Biocompatibility, including Degradation Testing:

Comprehensive biocompatibility testing of the TRS C-BVF material demonstrates that it is biocompatible; non-genotoxic, non-pyrogenic, non-toxic and a non-irritant. See Table 6-3 for the specific tests performed including the results and conclusions.

Results of the degradation testing, which included accelerated and real-time polymer degradation, as well as extreme simulation ceramic degradation, have shown comparable performance between the TRS and chronOS predicate device. Both devices demonstrated a similar PCL degradation mechanism by hydrolysis of the ester linkage to give a carboxylic acid and an alcohol as by products. In addition, similar trace elements were detected for both devices. Molecular ions detected from the extracts from both devices at 90-day real-time test demonstrated similar retention times, and indicate the degraded compounds are similar or related. These results provide further evidence that the TRS C-BVF is substantially equivalent to the chronOS predicate device.

While degradation testing was not performed on the OsteoPore PCL Scaffold predicate device, an infrared analysis of both the TRS C-BVF device and the OsteoPore PCL Scaffold device was undertaken using Fourier Transform Infrared Spectroscopy (FTIR) to qualitatively establish similarity of PLC polymeric material components between these devices. FTIR results for both TRS device and Osteopore PCL Scaffold showed strong peaks

consistent with traditional peaks found in the infrared spectra of PCL indicated that PCL is a major component for these devices. (See Section 11.4 of this 510(k) submission and Appendix B, Tab B-5 for a summary of this testing.) Given that both the TRS C-BVF device and the OsteoPore PCL Scaffold predicate are composed of Poly-ε-caprolactone material, degradation results for the OsteoPore material are presumed substantially similar to the TRS C-BVF device.

In conclusion, the TRS C-BVF device is biocompatible and demonstrates comparable degradation performance to the predicate devices, supporting a claim of substantial equivalence to the predicate chronOS and OsteoPore PCL Scaffold devices.

Table 6-3: Biocompatibility Tests, Results and Conclusions

ISO 10993 Standard	Test	Results	Conclusions
10993-5	Cytotoxicity (ISO Elution Method- 1X MEM Extract)	No cytoxicity or cell lysis was noted in any of the test wells. No pH shift was observed at 48 hours. Reactivity grade was 0 (none).	Non-cytotoxic
10993-10	Sensitization (Guinea pig maximization sensitization test)	All Animals were clinically normal throughout the study. Test article extracts showed no evidence of causing delayed dermal contact sensitization in guinea pig.	Non-sensitizer
10993-10	Intracutaneous Reactivity	There was no erythema and no edema from the 0.9% sodium chloride solution test extract. There was very slight erythema and very slight edema from the sesame oil test extract. However, the difference from the control was 1.0 or less.	Non-irritant
10993-11	Systemic Toxicity (Acute systemic toxicity in mice)	There was no mortality or evidence of systemic toxicity from the test extracts. Body weight data were acceptable.	No acute systemic toxicity
10993-3	Genotoxicity (Gene mutation): Bacterial Reverse Mutation study	The DMSO and saline extracts from TRS device were considered to be non-mutagenic to *Salmonella typhimurium* tester strains TA98, TA100, TS1535, and TA1537, and to *Escherichia coli* tester strain WP2*uvrA*.	Non-mutagenic
10993-3	Genotoxicity (*in-vivo*; Mouse Peripheral Blood Micronucleus Study)	The saline and sesame oil test extracts did not induce micronuclei in mice. There were no statistically significant differences between the test and negative control groups.	Non-clastogenic
10993-3	Genotoxicity (Mouse Lymphoma Assay)	The undiluted $RPMI_0$ and 1.0% DMSO TRS device extracts did not cause any positive increase in the mean mutant frequency in the L5178Y/$TK^{+/-}$ cell line either in the presence or absence of metabolic activation.	Non-mutagenic
10993-6	Local effects after Implantation (Muscle implantation study in rabbits-2 weeks)	The macroscopic reaction of TRS device was not significant as compared to the ChronOS and negative control (HDPE). Microscopically, TRS device was classified as a non-irritant as compared to ChronOS and HDPE.	Non-irritant as compared to the negative control (HDPE) and predicate device (ChronOS)

ISO 10993	Test Description	Results	Conclusions
10993-6	Local effects after Implantation (Muscle implantation study in rabbits-6 weeks)	The macroscopic reaction of TRS device was not significant as compared to the ChronOS and negative control (HDPE). Microscopically, TRS device was classified as a non-irritant as compared to ChronOS and a slight irritant when compared to HDPE.	Non-irritant as compared to the predicate device (ChronOS) and a slight irritant when compared to the negative control (HDPE)
10993-11	Systemic toxicity (USP Pyrogen study)	One (out of 3) of the animals showed a rise of 0.5°Cabove its baseline temperature. The result was inconclusive and the protocol required 5 additional animals to be injected.	Inconclusive – retest required
10993-11	Systemic toxicity (USP Pyrogen study-retest)	A total of 3 out of 8 rabbits had a temperature rise of ≥ 0.5°C , and the total temperature rise of the 8 animals did not exceed 3.3°C. The USP test requirement was met. TRS device was considered non-pyrogenic.	Non-pyrogenic
10993-11	Systemic toxicity: Sub-chronic toxicity (13 week study in rats following subcutaneous implantation)	No evidence of systemic toxicity from TRS device following subcutaneous implantation in the rat. Daily clinical observations, body weights, necropsy findings, organ weights and organ/body weight ratios were within acceptable limits and were similar between TRS device and control (HDPE) treatment group. There were no changes in histopathology, hematology values or clinical chemistry values in either male or female rats. Microscopic evaluation of the selected tissues revealed no evidence of a treatment related response. Microscopic evaluation of the implant sites revealed that the test implant site scores were higher than control implant site scores.	No evidence of systemic toxicity, local macroscopic tissue reaction not significant as compared to HDPE control, microscopically classified as slight irritant as compared to HDEP control
10993-11	Systemic toxicity: Chronic toxicity (26 week study in rats following subcutaneous implantation)	No evidence of systemic toxicity from TRS device following subcutaneous implantation in the rat. Daily clinical observations, body weights, necropsy findings, organ weights and organ/body weight ratios were within acceptable limits and were similar between TRS device and control (HDPE) treatment group. There were no changes in histopathology, hematology values or clinical chemistry values in either male or female rats that were considered to be biologically significant or related to treatment with TRS device. Microscopic evaluation of the selected tissues revealed no evidence of a treatment related response. Microscopic evaluation of the implant sites revealed that the test implant site scores were higher than control implant site scores	No evidence of systemic toxicity, local macroscopic tissue reaction not significant as compared to HDPE control, microscopically classified as moderate irritant as compared to HDPE control. The degrading sample elicited an expected mild macrophage/giant cell response.
10993-4	ASTM F756 Hemolysis Test – Direct contact and extract test	The hemolytic index of the test article in direct contact with blood was 0.4% and the hemolytic index for the test article extract was 0.1%. The test article in direct contact with blood and the test article extract were both non-hemolytic.	Non-hemolytic
ASTM F2382	Partial Thromboplastin Time (PTT)	Average clotting time of the test article was 77% of the negative control	Passed as a minimal activator of the intrinsic coagulation pathway (ASTM F2382 defines the test result of > 50% of the negative control as a passing result)

ISO 10993	Test Description	Results	Conclusions
10993-4	C3a Complement Activation Assay	C3a concentration of the test article was statistically significantly higher than the activated NHS (normal human serum) control and negative control (low density polyethylene).	Complement activation by a device is primarily a surface related phenomenon. As TRS is not a direct blood-contacting device, there is no direct interaction of the blood with the surface of the device.
10993-4	SC5b-9 Complement Activation Assay	SC5b-9 concentration of the test article was statistically significantly higher than the activated NHS (normal human serum) control and negative control (low density polyethylene).	Complement activation by a device is primarily a surface related phenomenon. As TRS is not a direct blood-contacting device, there is no direct interaction of the blood with the surface of the device.
10993-13	Identification and quantification of degradation products from polymeric devices (Real time polymer degradation Polymer: 30,90,180,365,540, and 730 days)	After incubation in phosphate buffered saline (PBS) at 37 °C, TRS C-BVF lost 10% and 23% of its molecular weight and 0.26% and 0.47% of its initial mass at 365 and 730 days, respectively. Extracts of TRS device revealed one compound (2-hexenoic acid, butyl ester, (E)-) at 30, 90, 180, and 365 day at a concentration in the range of 2-6 ppm. ChronOS composite resulted in one compound (di-n-octyl phthalate) detected in the 30 day replicate 2 extract. The average molecular weight (M_w) shows that TRS devices were unchanged after 30 days, but did exhibit degradation by 90 days with approximately 5% reduction in average molecular weight. M_w at 365 days showed a decrease of approximately 5%with a similar trend for the later time points. The ChronOS composite, on the other hand, exhibited a 57% reduction in average molecular weight by 30 days and a considerable 90% reduction by 90 days, 95% at 180 days, 98% by 365 days, and was completely degraded prior to the 540 day time point. The decrease in pH of the solution of ChronOS composite, may have affected the degradation profile. The number average molecular weight (Mn) showed that the Mn of TRS device decreased approximately 10% over 365 days and further decreased to 23% after 730 days. No other compounds were detected at any other time point above the quantitation limit.	TRS device real time degradation results demonstrated that the device is in the first stage of degradation with the decrease in molecular weight without mass loss and deformation. (Additional detail to following in Executive Summary)
10993-14	Identification and quantification of degradation products from ceramics (extreme/simulation)	The extreme solution test caused approximately 26-27% of the ceramic and hydroxylapatite to dissolve from both the coated and uncoated discs. After the testing had been performed, the buffer solutions showed the presence of calcium, magnesium, phosphorus, sulfur, and in some cases aluminum, barium, and iron. The simulation solution test caused a mass loss of less than 1% for both coated and uncoated discs. The solutions after the simulation test contained calcium and phosphorus for both sample types. In the case of the coated discs, magnesium and sodium were also observed. The SEM images for the coated samples after the simulation test still showed the flake-like structure, but some erosion was apparent. After the simulation test, no significant differences in the EDS data were observed, as compared to the coated samples that had not been subjected to the simulation test.	Both extreme and simulation test demonstrated that the ceramic component of TRS device is composed of calcium and phosphate ceramic. Quantitative analysis of four individual heavy metal elements (As, Cd, Pb, Hg) was within acceptable limit as stated in ISO 13779. (Additional detail to following in Executive Summary)

9.2 Bench Testing:

Bench testing to evaluate the compressive mechanical properties and push out force of the TRS C-BVF, the chronOS and Ostepore devices showed comparable performance and demonstrated that the TRS C-BVF device to possess appropriate performance characteristics for its intended use. In addition, material testing using FTIR demonstrated the same PCL material composition in both the predicate Osteopore PCL Scaffold device and the TRS C-BVF device. These results provide further technical evidence supporting a claim of substantial equivalence between the subject and predicate devices.

9.3 Animal Testing:

Results of the Rabbit Calvarial Defect testing have demonstrated similar performance of the TRS C-BVF and predicate chronOS devices with respect to new bone formation. By 26 weeks, total bone formation in both the subject and predicate devices was approximately equal and by 78 weeks, CT showed bone volumes for both devices to be nearly identical. The data shows that TRS C-BVF facilitates a constant, sustained bony healing response over time. Results of this testing demonstrate that the TRS C-BVF performs in a similar manner to the predicate chronOS device in a cranial defect in an animal model. This testing provides further technical evidence that the TRS C-BVF device performs comparably to the predicate chronOS device and provides additional support to a claim of substantial equivalence to the predicate devices.

9.4 Clinical (Literature):

The clinical literature summarized utilizes PCL in a number of material forms and indications. Clinical studies reported good outcomes in applied applications, expected absorption rates and with no reported material-mediated complications.

No clinical studies have been performed in support of this 510(k) application due to the similarities of the TRS C-BVF to the predicate devices. Further, the constituent materials of the subject device have a long history of safe and successful clinical use in numerous implantable medical applications as identified above. The PCL containing materials and material combinations referenced in this literature are comparable to that utilized in the TRS C-BVF. As such, the reported successful clinical history provides evidence of PCL's safety profile in clinical use and is representative of the expected safety profile for TRS C-BVF.

10.0 Conclusion

Product characterization and testing on the TRS Cranial Bone Void Filler when compared to its predicate devices demonstrate that it is substantially equivalent to the Osteopore PCL Scaffold Bone Void Filler, Synthes chronOS, Synthes chronOS Composite and Synthes Rapid Resorbable Cranial Clamp devices, commercially available cranial burr hole covers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Tissue Regeneration Systems, Inc.
Mr. William J. Fitzsimmons
President and Chief Executive Officer
5400 Carillon Point
Kirkland, WA 98033

Re: K123633
Trade/Device Name: Tissue Regeneration Systems Cranial Bone Void Filler (TRS C-BVF)
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: July 10, 2013
Received: July 18, 2013

Dear Mr. Fitzsimmons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123633

Device Name: Tissue Regeneration Systems Cranial Bone Void Filler (TRS C-BVF)

Indications For Use:

TRS C-BVF is intended for use in the repair of 13 mm neurosurgical cranial burr holes. It should be gently packed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang -S

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K123633